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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' REPLY IN
SUPPORT OF MOTION FOR
SUMMARY JUDGMENT AS TO
PLAINTIFF DEBRA MULKEY'S
CLAIMS**

DEBRA MULKEY, an individual,

(Assigned to the Honorable David G.
Campbell)

Plaintiff,

(Oral Argument Requested)

v.

C. R. BARD, INC., a New Jersey
corporation and BARD PERIPHERAL
VASCULAR, INC., an Arizona
corporation,

Defendants.

1 Plaintiff seeks to avoid summary judgment on all of her claims by (a) ignoring
 2 clear and unequivocal testimony in the record, (b) asking this Court to recognize legal
 3 duties not previously recognized under Kentucky law, (c) asking this Court to recognize
 4 causes of action not previously recognized under Kentucky law, and (d) jumping to legal
 5 conclusions based on facts that do not support Plaintiff's logical leaps. As explained in
 6 Bard's opening brief (Doc. 7334), and as explained in further detail below, Bard is
 7 entitled to judgment as a matter of law as to all of Plaintiff's claims.¹

8 **A. The 1-Year Kentucky Statute of Limitations Bars Plaintiff's Claims.**

9 **i. Plaintiff Knew of Her "Fact of Injury" on October 4, 2012.**

10 Plaintiff does not dispute that she subjectively knew on October 4, 2012, that her
 11 physician could not remove her Eclipse Filter. She does not dispute her knowledge that
 12 her physician was having "problems" when he tried to remove her filter. (Mulkey Dep.
 13 Tr., at 99:7-10 (attached as Ex. E to Defs. SSOF).) She does not dispute or attempt to
 14 explain her testimony that she was "upset" on October 4, 2012, when she learned that her
 15 filter could not be removed. (*Id.* at 185:3-9.) And she does not dispute her testimony that
 16 the first time she experienced symptoms of any "bodily injuries" was on October 4, 2012,
 17 the day of her unsuccessful removal surgery. (*Id.* at 142:8-24.) Nonetheless, Plaintiff
 18 claims that the discovery rule should toll the running of the statute of limitations until
 19 October 2015, when she "saw a commercial on TV that indicated that IVC filters were
 20 causing bodily injuries to people." (PFS at § II.13(c) (attached as Ex. A to Defs.' SSOF).)
 21 Plaintiff's arguments are incorrect. A plaintiff merely needs to know (or reasonably
 22

23 ¹ As part of her response papers, Plaintiff filed a 17-page "Controverting Statement of
 24 Facts" (Doc. 7946), and she relies on a 52-page "Omnibus Separate Statement of Facts"
 25 (Doc. 7950). The District of Arizona Local Rule 56.1(b) does not require a moving party
 26 to reply to a "controverting statement of facts" or respond to a non-moving party's
 27 "additional facts." Accordingly, Bard is not filing such a reply or response here. As noted
 28 throughout this Reply Brief, however, these allegations do not raise a genuine issue of
 material fact that would preclude summary judgment. Instead, Plaintiff's reference to
 these allegations appears to be largely an attempt to "pack" the summary judgment record
 with irrelevant allegations (e.g., allegations about filters that Plaintiff did not receive). To
 be clear, Bard disagrees with Plaintiff's characterization of many of these alleged "facts,"
 even if such disagreement does not raise a genuine issue of material fact.

1 should know with the exercise of reasonable diligence) of the “fact of injury” for the
2 statute to start running. *Fluke Corp. v. LeMaster*, 306 S.W.3d 55, 60 (Ky. 2010); *see also*
3 *Bridgefield Cas. Ins. Co. v. Yamaha Motor Mfg. Corp. of Am.*, 385 S.W.3d 430, 433 (Ky.
4 Ct. App. 2012) (same); *Bosch v. Bayer Healthcare Pharm., Inc.*, 13 F. Supp. 3d 730, 737
5 (W.D. Ky. 2014) (same).

6 Plaintiff argues that the discovery rule should apply because she did not know she
7 was “wronged” until October 2015, (*see* Pl.’s Resp. at 4), which is the time when she saw
8 a TV advertisement soliciting potential IVC filter plaintiffs. Contrary to Plaintiff’s
9 argument, her injury—that is, the fact that her IVC filter could not be removed—is not the
10 type of “inherently unknowable” injury that may trigger the discovery rule. *See Davis v.*
11 *All Care Med., Inc.*, 986 S.W.2d 902, 906 (Ky. 1999) (noting that the discovery rule
12 applies in cases that “center around injuries of an inherently unknowable nature”).

13 Plaintiff relies heavily on *Wiseman v. Alliant Hospitals, Inc.*, 37 S.W.3d 709 (Ky.
14 2000) in arguing that the discovery rule should apply. *Wiseman*, and other “foreign
15 object” or “latent injury” cases are readily distinguishable from this case.² In *Wiseman*,
16 the plaintiff did not know that her doctor left a foreign object (a piece of a metal medical
17 instrument) in her body until almost seven years after her procedure. *See id.* at 711. Thus,
18 the plaintiff’s knowledge base in 1989 (when she had her procedure) was fundamentally
19 different than her knowledge base in 1996 (when she learned for the first time that a
20 foreign object was left in her body). Here, no such fundamental change in Plaintiff’s
21 knowledge base occurred between October 4, 2012 (the date of her unsuccessful removal
22

23 ² Plaintiff argues that she sustained a “latent injury.” (Pl.’s Resp. at 6.) She is mistaken.
24 The Sixth Circuit in *Asher v. Unarco Material Handling, Inc.*, 596 F.3d 313 (6th Cir.
25 2010), applying Kentucky law, explained the difference between latent injury and non-
26 latent injury cases. In the former, a plaintiff’s injuries or symptoms do not manifest until
27 years after exposure to a product. *See id.* at 321 (citing the asbestos/mesothelioma case of
28 *Louisville Tr. Co. v. Johns-Manville Prod. Corp.*, 580 S.W.2d 497 (Ky. 1979) as an
example of a latent injury case). In contrast, a non-latent injury case is when a plaintiff’s
injuries or symptoms “manifest[] immediately.” *Asher*, 596 F.3d at 321. Here, Plaintiff
admits that she first experienced “symptoms” of her “bodily injuries” on October 4, 2012,
the day of her removal procedure. (Mulkey Dep. Tr., at 142:8-24 (attached as Ex. E to
Defs.’ SSOF).)

1 surgery) and October 2015 (the date when she saw the advertisement). At both points in
 2 time, Plaintiff knew that her Eclipse Filter could not be removed. The *only difference* is
 3 that in October 2015, Plaintiff saw a law firm advertisement that told potential IVC filter
 4 plaintiffs to call a toll-free number, which Plaintiff did. Plaintiff fails to point to any other
 5 evidence—such as a doctor’s advice, a publicly issued notice regarding IVC filters, etc.—
 6 that she claims triggered her discovery of her “injury.” Plaintiff also fails to cite any
 7 authority for her novel legal position applying the discovery rule when, as in this case, the
 8 plaintiff knew of the facts of the alleged injury, but did not subjectively believe she was
 9 wronged until seeing a TV advertisement soliciting potential plaintiffs.

10 Plaintiff’s argument is, in essence, that the discovery rule should toll the running of
 11 the statute of limitations until she subjectively knew she may have a claim against Bard
 12 (i.e., in October 2015 after seeing the TV advertisement). She attempts to rely on
 13 Kentucky’s distinction between discovery of an “injury” versus “harm,” (*see* Pl.’s Resp. at
 14 2), and then focuses on her subjective knowledge of her alleged injury. (*See, e.g.*, Pl.’s
 15 Resp. at 3 (“Ms. Mulkey did not believe there was anything defective about her filter.”; *id.*
 16 at 4 (“Ms. Mulkey did not believe she had been wronged by the manufacturer of the IVC
 17 filter, Bard.”).) Plaintiff’s emphasis on her subjective knowledge is misplaced. In
 18 Kentucky, “[t]he discovery rule focuses not on when a plaintiff has actual knowledge of a
 19 legal cause of action, but whether a plaintiff acquired knowledge of existing facts
 20 sufficient to put the party on inquiry.” *Blanton v. Cooper Indus., Inc.*, 99 F. Supp. 2d 797,
 21 802 (E.D. Ky. 2000). Thus, contrary to Plaintiff’s suggestion, “[t]he date that a party
 22 ‘discovers’ that he or she may sue for a wrong is not considered.” *Id.* at 801.

23 The Kentucky Court of Appeals recently addressed, and rejected, a similar
 24 argument to the one advanced by Plaintiff here. In *Wells v. Trover*, No. 2012-CA-001885-
 25 MR, 2016 WL 99824 (Ky. Ct. App. Jan. 8, 2016), the court held that a plaintiff’s claim
 26 accrued on the date that a radiologist misread the plaintiff’s x-ray revealing a broken
 27 bone, not years later when the plaintiff first learned of a putative medical malpractice
 28 class action against the physician. *See id.* at *2-3. The plaintiff argued that although she

1 knew she had been harmed in 2001, “she did not know she had been injured or wronged
2 (*i.e.*, that someone had invaded her legally protected interests) until March 2004 when the
3 article in the Madisonville Messenger was released informing the public of Dr. Trover and
4 the Foundation’s alleged negligence.” *Id.* at *2. Thus, according to the plaintiff in *Wells*,
5 her filing of her lawsuit against the physician in 2005 was timely. *See id.* Rejecting this
6 argument, the Kentucky Court of Appeals stated, “[t]he error in her reasoning is not
7 uncommon, but the fact remains that *legal* confirmation that one has been wronged is not
8 necessary under the discovery rule.” *Id.* at *3 (emphasis in original). “The rule merely
9 requires that one be aware of the facts sufficient to put her on notice that her legal rights
10 may have been invaded and by whom; uncertainty about the *legal* significance of those
11 facts does not toll the limitations period.” *Id.* (emphasis in original).

12 Plaintiff’s argument seeking to expand the discovery rule also disregards the fact
13 that Kentucky’s application of the discovery rule is narrow. *See, e.g., Asher v. Unarco*
14 *Material Handling, Inc.*, 596 F.3d 313, 322 (6th Cir. 2010) (“Kentucky’s courts have
15 cautioned against judicial efforts to expand the discovery rule without legislative
16 authorization.”). Almost 50 years ago, the Kentucky Supreme Court explained the policy
17 rationale behind adopting the discovery rule: “Courts have felt that the injured party
18 should be allowed to have his day in court *when his injury was of an inherently*
19 *unknowable nature.*” *Louisville Tr. Co. v. Johns-Manville Prod. Corp.*, 580 S.W.2d 497,
20 501 (Ky. 1979) (emphasis added). The court also explained the rationale for applying the
21 discovery rule when the “causal relationship” between the defendant’s product and the
22 plaintiff’s injury “do not occur simultaneously.” *Id.* However, mere erroneous
23 assumptions or mistaken beliefs about the cause of a plaintiff’s injury are not sufficient to
24 trigger the discovery rule. *Asher*, 596 F.3d at 322 (affirming district court’s grant of
25 summary judgment on a statute of limitations defense, where the plaintiffs were exposed
26 to carbon monoxide and immediately manifested symptoms, but believed that the
27 symptoms were caused by influenza).

28 At bottom, the discovery rule should not be used as a tool for a plaintiff to

1 indefinitely toll the statute of limitations until the date she sees a TV advertisement
 2 soliciting potential plaintiffs. Extending the discovery in such a manner would contravene
 3 the policies undergirding the discovery rule, and would be inconsistent with Kentucky's
 4 narrow application of the rule. Because Plaintiff knew on October 4, 2012, of her "fact of
 5 injury," the discovery rule does not apply, and her claims are time-barred.³

6 **ii. Plaintiff Had a Duty to Inquire About Her Device, and She Failed to**
 7 **Discharge That Duty.**

8 Plaintiff also argues that she had no duty to inquire as to the safety of her device.
 9 (Pl.'s Resp. at 5-7.) To support her argument, Plaintiff relies heavily on *Roberts v. Stryker*
 10 *Corp.*, No. CIV.A. 10-116-HRW, 2011 WL 2912697 (E.D. Ky. July 18, 2011). *Roberts* is
 11 distinguishable from this case. *Roberts* was decided on a Rule 12(b)(6) motion to dismiss.
 12 *See id.* at *1. Thus, the court did not have a factual record to review, but, instead, accepted
 13 as true the plaintiff's factual allegations. The plaintiff in *Roberts* had a history of shoulder
 14 problems *before* he received the defendant-manufacturer's shoulder pain pump. *See id.* at
 15 *3. This fact was critical to the court's reasoning, and it concluded, based on that fact, that
 16 the plaintiff "had absolutely no reason to associate [shoulder] problems with the use of a
 17 pain pump or to suspect that the pain pump was somehow defective." *Id.*

18 Here, in contrast to *Roberts*, Plaintiff plainly did not have a history of having an
 19 IVC filter that could not be removed, which is the alleged injury she suffered. Instead, she
 20 was upset and knew her physician had problems attempting to remove her device.
 21 Plaintiff's subjective knowledge on October 4, 2012, that her filter could not be removed
 22 should have "excite[d] [her] suspicion" such that she effectively had at that time "actual

23 ³ In a footnote, Plaintiff suggests that this Court should reject Bard's statute of limitations
 24 arguments because this is a bellwether case. (Pl.'s Resp. at 1 n.1.) Plaintiff cites no
 25 precedent or authority for a court to reject an otherwise meritorious argument that would
 26 dispose of a case merely because it is a bellwether case. Moreover, Plaintiff's argument is
 27 based on a false assumption: That her case, with a meritorious statute of limitations
 28 defense, is not representative of a significant portion of the 323 cases in the Discovery
 Group Pool 1. To the contrary, Bard has conducted a preliminary statute of limitations
 assessment of the 323 cases in Pool 1 and has determined that approximately 84 of the
 cases—or 26% of the 323—have potential statute of limitations defenses. Accordingly,
 Plaintiff's case, and Bard's meritorious statute of limitations defense, is representative of a
 significant percentage of the Pool 1 cases.

1 knowledge of [her] entire claim.” *LeMaster*, 306 S.W.3d at 64. Consistent with Kentucky
2 law, on October 4, 2012, Plaintiff had a duty to “inquire into the safety of [her Filter]” to
3 determine whether the “product may have been a potential cause of an injury.” *Id.*

4 Finally, the record is clear that before October 2015, Plaintiff took **no action** to
5 attempt to discover whether she had been injured. But before the Kentucky discovery rule
6 can even be applied, a plaintiff must first exercise “reasonable diligence” to discover her
7 injury, which means investigation that “must be more than merely perfunctory.” *Blanton*,
8 99 F. Supp. 2d at 802 (internal citations and quotation marks omitted); *Manning v. Arch*
9 *Wood Prot., Inc.*, No. CV 13-127-HRW-CJS, 2016 WL 7910818, at *4 (E.D. Ky. Aug.
10 30, 2016) (same). “Plaintiffs may not close their eyes to means of information reasonably
11 accessible to them and must in good faith apply their attention to those particulars which
12 may be inferred to be within their reach.” *Blanton*, 99 F. Supp. 2d at 802. “[P]otential
13 plaintiffs cannot simply wait for someone else to connect the dots for them.” *Manning*,
14 2016 WL 7910818, at *4.

15 Here, Plaintiff failed to exercise reasonable diligence. She waited until October
16 2015 for a TV advertisement soliciting potential IVC filter plaintiffs to “connect the dots”
17 for her. Her “failure to make any inquiry despite having sufficient information available to
18 [her] is deemed a failure to exercise reasonable diligence as a matter of law.” *Blanton*, 99
19 F. Supp. 2d at 803. The discovery rule does not apply to Plaintiff’s claims. Instead, her
20 claims are time-barred by Kentucky’s 1-year statute of limitations.

21 **B. Plaintiff Fails to Identify a Genuine Dispute as to Any Material Fact**
22 **Regarding Her Failure to Warn Claim.**

23 **i. Plaintiff Cannot Prove Causation.**

24 Plaintiff’s implanting physician, Dr. Tompkins, testified under oath unequivocally
25 that he does not rely on information from a medical device manufacturer in deciding
26 which IVC filter to use. His precise testimony, which was elicited by Plaintiff’s counsel
27 on direct examination, is as follows:
28

19 Q So -- so in -- in deciding which --
 20 which filter to use, *do you rely on information*
 21 *from the manufacturer?*
 22 A No.

(Tompkins Dep. Tr., at 88:19-22 (attached as Ex. C to Defs.' SSOF) (emphasis added).)
 Dr. Tompkins also testified that he would be speculating as to whether the alleged factual
 information presented to him by Plaintiff's counsel would have altered his treatment
 decision for Plaintiff. (See Tompkins Dep. Tr., at 184:13 to 185:16 (attached as Ex. C to
 Defs.' SSOF ("Q Okay. So -- so again, being shown a draft e-mail and asked if you had
 known, if you had known, would you have made a different decision, *you're really*
speculating, aren't you? MR. DeGREEFF: Object to the form. A *Yes.*" (emphasis
 added)).)

Plaintiff's Response Brief ignores Dr. Tompkins's testimony above. Instead of
 addressing that testimony, Plaintiff offers six bullet points of other testimony of Dr.
 Tompkins that she alleges demonstrates proximate causation. (See Pls. Resp. at 12-13.) A
 close inspection of that testimony, however, reveals that it *does not* establish causation for
 two reasons.

First, many of Plaintiff's bullet points do not relate to the issue of causation. For
 instance, Plaintiff states "[t]here were risks and problems with Bard's filters that Bard did
 not tell Dr. Tompkins about." (Pls. Resp. at 12.) This assertion relates to whether Bard's
 warnings were legally adequate—and they were, as demonstrated at Section A.ii., *infra*—
 not causation. Plaintiff's bullet point numbers one and five suffer from this same logical
 flaw.

Second, the three bullet points that Plaintiff lists that do relate to causation do not
 establish that an alleged inadequate warning was the proximate cause of Plaintiff's
 injuries (i.e., that a proper warning would have changed Dr. Tompkins's treatment
 decision). The first bullet point is that "[i]f Dr. Tompkins had expected these issues [tilt,
 perforation, and irretrievability] to occur, he would not have used the filter." (Pls. Resp. at
 12.) But Dr. Tompkins did not testify that he, in fact, expected those issues to occur after

1 seeing the documents shown to him by Plaintiff’s counsel. Instead, he recognized that
 2 “[u]nfortunately, there’s complications with any product.” (Tompkins Dep. Tr., at 99:10-
 3 11 (attached as Ex. M-C to Pls.’ OSOF).) Moreover, Plaintiff fails to cite anything in the
 4 record that Bard’s Eclipse Filter *is expected* to tilt, perforate, or be unable to be retrieved.
 5 Thus, Plaintiff has failed to link Dr. Tompkins’s testimony relating to causation (i.e., that
 6 he would have used another device if he “expected” complications to occur with Plaintiff)
 7 with the underlying factual predicate (i.e., that it was expected that the filter would cause
 8 complications with Plaintiff).

9 The second bullet point is that “[i]f the Eclipse had a significantly increased risk of
 10 migration over other filters . . . [Dr. Tompkins] wouldn’t use the filter.” (Pls. Resp. at 13.)
 11 Again, Plaintiff fails to present evidence of the underlying factual predicate, that is, that
 12 the Eclipse allegedly has a significant increased risk of migration over other filters. While
 13 Plaintiff cites evidence *of other Bard IVC filters* (e.g., Recovery) allegedly having higher
 14 migration rates compared to other filters, she does not cite the same kind of evidence for
 15 the Eclipse.⁴ Additionally, Dr. Tompkins never quantifies what a “significant increased
 16 risk” means to him.

17 The third bullet point that Plaintiff offers is that “Dr. Tompkins would not have
 18 implanted the Eclipse filters had he been informed that there were deaths occurring
 19 concurrently.” (Pls. Resp. at 13.) Like the other two bullet points above, this argument
 20 assumes a factual predicate—that, at the time he implanted an Eclipse Filter in Plaintiff,
 21 there were “deaths occurring concurrently” with Eclipse—that is not in the record.
 22 Nowhere in Plaintiff’s Response Brief or in Plaintiffs’ 52-page omnibus statement of facts
 23 does Plaintiff cite to record evidence demonstrating that deaths were occurring with the
 24 Eclipse Filter in or around April 2012, when Plaintiff received her device.

25
 26 ⁴ At most, Plaintiff references evidence relating to the comparative *fracture* rate of
 27 Eclipse compared to the SNF. (See Pls.’ OSOF at ¶ 114.) But Dr. Tompkins’s testimony
 28 concerning whether he would use a different device is only in the context of *migration*,
not fracture. (See Tompkins Dep. Tr., at 108:10 to 109:1 (attached as Ex. M-C to Pls.’
 OSOF).)

Finally, Plaintiff cites the Tenth Circuit Court of Appeals decision in *Tingey v. Radionics*, 193 Fed. App'x 747 (10th Cir. 2006) for the proposition that, in deciding causation, the relevant inquiry is “[c]ould an adequate warning have prevented Ms. Mulkey’s injury.” (Pls. Resp. at 12.) Plaintiff’s reliance on *Tingey* is misplaced for two reasons. First, the Tenth Circuit in that case applied *Utah law, not Kentucky law*. See generally *Tingey*, 193 Fed. App'x 747. Second, the standard for the burden of proof for Plaintiff to prove causation in Kentucky is the preponderance of the evidence, i.e., more likely than not. As one court has said, causation “must be established by a preponderance of the evidence—‘the evidence must be sufficient to tilt the balance from possibility to probability.’” *Paducah & Louisville Ry., Inc. v. Quixx Corp.*, No. CIV.A. 4:04CV00176, 2007 WL 2746673, at *2 (W.D. Ky. Sept. 18, 2007), *aff’d*, 294 F. App'x 995 (6th Cir. 2008) (quoting *Morales v. Am. Honda Motor Co.*, 151 F.3d 500, 507 (6th Cir. 1998)). Accordingly, whether a different warning *could have* changed Dr. Tompkins’s treatment decision is not the proper inquiry. Instead, the relevant question is whether a different warning *would have probably* changed his decision. Dr. Tompkins testimony cited above that he does not rely on information from a manufacturer when deciding which IVC filter to use forecloses any such probability.

ii. Bard’s Warnings Are Legally Adequate.

Bard provided legally adequate warnings to Dr. Tompkins concerning the possible risks associated with use of the Eclipse Filter. Plaintiff admits that Bard’s Eclipse IFU warns of the risks of filter tilt, migration, fracture, perforation, and inability to retrieve. (Pl.’s Resp. at 9.) Arguing that these warnings are legally inadequate, Plaintiff relies on *Post v. Am. Cleaning Equip. Corp.*, 437 S.W.2d 516 (Ky. 1969). (See Pl.’s Resp. at 9, 11.) The rule from *Post* is that a manufacturer’s duty to warn is discharged by providing “fair and adequate notice of the *possible consequences* of use or even misuse” of a product. *Post*, 437 S.W.2d at 522 (emphasis added).

Plaintiff’s various bullet points of alleged facts that Bard did not include in its IFU are not “potential consequences” of the use (or even misuse) of the Eclipse Filter. Indeed,

of the 16 bullet points that Plaintiff provides, 9 do not relate to the Eclipse Filter at all. They instead relate to other products (e.g., the Recovery Filter). The bullet points that do relate to the Eclipse Filter do not concern “possible consequences” with the device’s use. Five out of the six bullet points that do mention Eclipse relate to the device’s design or testing. (*See* Pl.’s Resp. at 10-11 (bullet points 6, 7, 8, 13, and 15⁵.) The remaining bullet point that specifically mentions Eclipse concerns comparative rates, which, as explained below, Bard has no legally recognized duty to warn about. (Pl.’s Resp. at 11 (bullet point 14 (“By June 2011, Bard was aware that the Eclipse, after only a little over a year on the market, fractured over 3 ½ times as often as the SNF.”).) Notably, Plaintiff does not dispute the fact that Bard warned physicians regarding the possible consequence of filter fracture. The final bullet point that Plaintiff provides concerns the theory that caudal migration may lead to filter tilt, perforation, irretrievability, or fracture. (*See* Pl.’s Resp. at 11 (bullet point 16).) Setting aside the accuracy of this theory,⁶ the ultimate possible consequences of filter use—filter tilt, perforation, irretrievability, or fracture—are all potential consequences (i.e., risks) that Bard warned about in the Eclipse IFU.

iii. No Court Applying Kentucky Law Has Recognized a Legal Duty to Warn About Another Product by Providing Comparative Rate Information.

Regarding Plaintiff’s argument that Bard should have provided comparative rate information in its warnings, Plaintiff cites no Kentucky precedent (or other authority applying Kentucky law) that recognizes a duty to warn about comparative rates. Providing comparative rate information necessarily requires providing information *about another product* (i.e., the device to which Bard is comparing the Eclipse). But no Kentucky court has recognized a legal duty to warn about another product.⁷

⁵ For example, Plaintiff states “Eclipse is essentially identical to the G2.” (Pl.’s Resp. at 10 (bullet point 6).) This is an alleged design feature of Eclipse.

⁶ Bard does not agree with Plaintiff’s characterizations and assertions of fact.

⁷ As discussed in greater detail in Bard’s Reply in Support of Its Motion for Summary Judgment Regarding Plaintiffs’ Jones, which Bard fully incorporates herein, there is no duty to provide comparative warnings, and the Court should decline to impose one here.

This is an issue concerning whether a legal duty exists in the first instance, not merely whether a warning is adequate.⁸ “In Kentucky, the existence of a duty is a matter of law for the court because [w]hen a court resolves a question of duty it is essentially making a policy determination.” *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 533 (Ky. 2003) (internal quotation marks omitted; alteration in original); *see also Cornett v. Labreuveux*, No. 2016-CA-000614-MR, 2017 WL 3328115, at *2 (Ky. Ct. App. Aug. 4, 2017) (“The question of whether a duty exists is a matter of law.”). Accordingly, because it is an issue of law, this Court, not a jury, should decide whether a medical device manufacturer has a legal duty to provide warnings regarding another product. In her Response Brief, Plaintiff invites this Court to be the first court in the country to make the policy determination that Kentucky should recognize such a duty. Bard respectfully asks this Court to decline that invitation. *See, e.g., Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397, 405 (6th Cir. 1990) (“The manufacturer is obligated to make a reasonable disclosure of all the risks inherent in its own drug It is not obligated to provide a comparison of its drug with others.” (applying Ohio law)); *Smith ex rel. Smith v. Wyeth Labs., Inc.*, No. CIV.A. 84-2002, 1986 WL 720792, at *9–10 (S.D. W. Va. Aug. 21, 1986) (rejecting argument that defendants had a duty to warn of adverse reaction rates as compared to competitor products, noting there is “no authority for the proposition that a drug manufacturer has a duty to warn prescribing physicians of the rate of adverse reactions” and “no authority for [the plaintiffs’] argument that a drug manufacturer may be required to represent that other drugs with similar effects are safer,” and “[a]s a practical matter, this would extremely difficult, perhaps impossible”).

C. Plaintiff’s Response Brief Fails to Raise a Genuine Issue of Material Fact Concerning Reliance, Which Forecloses Her Misrepresentation and Concealment Claims.

Plaintiff’s Response Brief ignores Dr. Tompkins’s testimony that he does not rely

⁸ In this regard, Bard respectfully suggests that the courts in *Cisson* and *Cason* mistakenly considered the existence of a legal duty as an issue concerning the adequacy of a warning. Thus, their reasoning that Bard’s warnings were inadequate because they did not include rate information is flawed. Moreover, neither *Cisson* nor *Cason* applied Kentucky law.

on information from a medical device manufacturer when deciding which IVC filter to use. (*See* Tompkins Dep. Tr., at 88:19-22 (attached as Ex. C to Defs.’ SSOF).) Instead, Plaintiff cites to testimony from Dr. Tompkins that he had seen the Eclipse IFU at some point in the past, but that he did not know if he “read every word in it.” (Tompkins Dep. Tr., at 105:15-18 (attached as Ex. M-C to Pls.’ OSOF).) Dr. Tompkins also testified that his practice is to “look [] over” the IFU for “a new device.” (*Id.* at 105:19-23.) But the fact that Dr. Tompkins may have seen and read portions of the Eclipse IFU does not mean he **relied** on it when he chose which IVC filter to use with Plaintiff. To the contrary, the only evidence in the record concerning what Dr. Tompkins relied on is his testimony that he relied on his experience, the experience of his colleagues, and the applicable medical literature when he decided to implant an Eclipse Filter in Plaintiff. (Tompkins Dep. Tr., at 202:7-22 (attached as Ex. C to Defs.’ SSOF).) Dr. Tompkins’s review of the Eclipse IFU does not create a genuine issue of material fact concerning the element of reliance.

Plaintiff’s Response Brief also ignores her own testimony that establishes that she did not rely on any misrepresentation or concealment by Bard. As noted by Bard in its Opening Brief, Plaintiff never received a patient card or brochure regarding her filter, never asked for any information about her filter before it was implanted, never spoke to anyone at Bard, never visited Bard’s website, and did not even know Bard was her filter’s manufacturer until her lawyer advised her long after she received her device. (Defs.’ Br. at 14 (citing Mulkey Dep. Tr., at 66:23 to 67:1, 67:11-18, 69:24 to 70:1, and 167:11-13 (attached as Ex. E to Defs.’ SSOF)).) Instead of addressing these facts, Plaintiff argues that she indirectly relied on alleged misrepresentations by relying on Dr. Tompkins’s professional medical advice. (Pls. Resp. at 14.)

Kentucky requires direct reliance, not indirect reliance, to support a misrepresentation or concealment claim. The Sixth Circuit stated succinctly, “Kentucky law requires **direct reliance** by the plaintiff on the defendant’s statements” to support a fraud claim. *Goldman Servs. Mech. Contracting, Inc. v. Citizens Bank & Tr. Co. of Paducah*, 9 F.3d 107, 1993 WL 428641, at *3 (6th Cir. 1993) (table decision) (emphasis

added); *see also Tunne v. Hendrick*, No. 5:10CV-00181-JHM, 2012 WL 3644825, at *4 (W.D. Ky. Aug. 24, 2012) (“Kentucky law requires direct reliance by a plaintiff on the defendants’ statements.”). Reliance on a third party (i.e., Dr. Tompkins), instead of the defendant (i.e., Bard), is not sufficient to establish the element of reliance. Again, the Sixth Circuit stated, “Kentucky law requires that the party claiming fraud show that he or she relied on the alleged misrepresentation, *not a third party*.” *Compressed Gas Corp. v. United States Steel Corp.*, 857 F.2d 346, 352 (6th Cir. 1988) (emphasis added). Accordingly, Plaintiff’s indirect reliance argument fails.⁹

Finally, the majority of Plaintiff’s argument on her misrepresentation and concealment claims focuses on the alleged misrepresentations or concealment of facts made by Bard. (*See* Pl.’s Resp. at 13-14.) Bard vehemently disputes Plaintiff’s characterization of these alleged misrepresentations or concealments of facts. But Bard’s Motion for Summary Judgment argument is based on the lack of reliance by Plaintiff and her implanting physician, not the lack of existence of a misrepresentation or concealment of fact.

D. Plaintiff Asks This Court to Create Post-Sale Duties That Have Been Previously Rejected by Other Courts.

The Kentucky Supreme Court in *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530 (Ky. 2003) conclusively rejected an independent post-sale duty to retrofit a product. *See id.* at 537. The Eastern District of Kentucky in *Cameron v. DaimlerChrysler Corp.*, No. CIV.A. 504CV24JMH, 2005 WL 2674990 (E.D. Ky. Oct. 20, 2005) similarly rejected a post-sale duty to warn. *See id.* at *7. No court has recognized a post-sale duty to recall in Kentucky, but the reasoning of *Cameron*, which applied *Ostendorf*, in rejecting a post-sale duty to warn applies equally to a post-sale duty to recall.

Plaintiff asks this Court to ignore the binding precedent of *Ostendorf* and recognize a post-sale duty to retrofit. Plaintiff argues that an independent duty to retrofit exists

⁹ Even if Plaintiff’s indirect reliance on Dr. Tompkins was relevant, as discussed above, Dr. Tompkins did not rely on Bard in choosing which filter to use.

1 because “[t]he Bard Eclipse was defective at the time it was sold.” (Pl.’s Resp. at 15.) This
 2 argument again ignores *Ostendorf*, when the Kentucky Supreme Court addressed and
 3 rejected this same argument, stating: “[T]here is a more fundamental reason to eschew
 4 imposition of a duty to retrofit: that duty is superfluous in light of existing negligence and
 5 product liability doctrines.” *Ostendorf*, 122 S.W.3d at 535. “When the case involves a
 6 retrofit, the plaintiff is claiming the product was defectively designed.” *Id.* A plaintiff in
 7 that scenario may bring suit for breach of warranty, negligence, or strict liability in tort.
 8 *Id.* Here, Plaintiff already has a remedy if her product is defective¹⁰; therefore, according
 9 to *Ostendorf*, no separate independent post-sale duty to retrofit exists.¹¹

10 Finally, Plaintiff claims that the device she received—an Eclipse Filter—is, itself,
 11 the product of a retrofit program. (Pl.’s Resp. at 16-17.) Plaintiff argues that “Bard
 12 undertook a voluntary retrofit campaign when it modified the predicate device, the G2X,
 13 to create the Eclipse Filter.” (Pl.’s Resp. at 16.) Plaintiff goes on to argue that Bard
 14 negligently undertook this “retrofit campaign.” (Pl.’s Resp. at 16-17.) Plaintiff’s argument
 15 misses the mark for two reasons. First, Plaintiff fails to cite any authority for her novel
 16 position that a product that happens to be a second generation (or later) product is, in and
 17 of itself, somehow a “retrofit campaign” that could subject a manufacturer to liability for
 18 the negligent undertaking of that campaign in a case involving that same device. Second,
 19 Plaintiff’s argument ignores the plain meaning of a “retrofit” campaign or program. Under
 20 Kentucky law, a “retrofit” program contemplates changes or modifications to the actual
 21 device at issue in the case. *Ostendorf* removes any doubt about this point. The court noted
 22 that “[a] duty to retrofit is an example of a *post-sale* obligation imposed on a
 23

24 ¹⁰ Bard strongly denies that the Eclipse Filter is defective or unreasonably dangerous.

25 ¹¹ Plaintiff also cites *Ostendorf* concerning the “analogous” cases cited by the court
 26 “imposing a duty to warn of later discovered defects.” (Pl.’s Resp. at 15.) Plaintiff fails to
 27 point out, however, that the *Ostendorf* court said in a footnote that “[t]he present case does
 28 not present the issue of a duty to warn. Our discussion addresses that topic only generally,
 as it relates to the issues in this case.” *Ostendorf*, 122 S.W.3d at 537 n.1. Thus, the court’s
 discussion of other cases identifying a duty to warn of later discovered defects is dicta.
See Cameron, 2005 WL 2674990 at *7 (“The court’s footnote makes it clear, therefore,
 that any discussion in *Ostendorf* concerning a post-sale duty to warn is dicta.”).

1 manufacturer.” *Ostendorf*, 122 S.W.3d at 536 (emphasis added). The court also described
2 a duty to retrofit “an existing product.” *Id.* at 533.¹² Accordingly, Kentucky law clearly
3 contemplates a claim for negligent undertaking of a retrofit campaign in the context where
4 a manufacturer produces a product, and then sometime later attempts to change or modify
5 (i.e., retrofit) that same product that is already in the hands of consumers. That is not what
6 has occurred in this case. Plaintiff has presented no evidence that Bard “retrofitted” her
7 Eclipse Filter after it was implanted in her body in April 2012. Her “negligent
8 performance” of a retrofit program fails as a matter of law.

9 **E. Plaintiff’s Negligence Per Se Claim Fails as a Matter of Law.**

10 Plaintiff’s Response Brief concedes that her negligence per se claim may not be
11 based on alleged violations of federal statutes or regulations.¹³ Plaintiff claims that her
12 negligence per se claim is based on violation of state law, specifically the Kentucky
13 Consumer Protection Act (“KCPA”). As demonstrated below, Plaintiff’s KCPA claim
14 fails as a matter of law, and, therefore, her negligence per se claim fails as a matter of law.

15 **F. Plaintiff Fails to Identify a Direct Representation to Her, Foreclosing**
16 **Any KCPA Claim as a Matter of Law.**

17 Plaintiff admits that privity of contract between the plaintiff and defendant is
18 ordinarily required to sustain a KCPA action. (Pl.’s Resp. at 18.) She argues, however,
19 that this case falls within an exception to that requirement because Bard made “express
20 representations” about her product. (*Id.*) Plaintiff’s argument fails for three reasons.

21 First, to the extent this exception even exists, Plaintiff downplays the requirement
22 for the exception to apply. She argues that “express warranties for the benefit of Kentucky
23

24 ¹² The retrofit program at issue in *Ostendorf* further illustrates this point. The product at
25 issue was a 1980 forklift C-300Y40, and the defendant-manufacturer had undertaken a
26 retrofit program to that model of forklift in 1983 following updates to relevant safety
27 standards for forklifts. *See id.* at 532-33.

28 ¹³ Plaintiff argues that “Ms. Mulkey’s negligence per se claim is . . . not based on a federal
statute of [sic] regulation.” But Plaintiffs’ Master Complaint makes clear that the
negligence per se claim is based on alleged “[v]iolations of 21 U.S.C. §§ 321, 331, 352 and
21 C.F.R. §§ 1.21, 801, 803, 807, 820.” (*See* Master Complaint for Damages for
Individual Claims [Dkt. No. 364] at Count IX.)

1 consumers” is sufficient. (Pl.’s Resp. at 18, 19.) Kentucky law requires more for the
 2 purported exception to the privity requirement to apply. For an express warranty to exist,
 3 Kentucky law requires “direct representations [to the plaintiff],” and the representations
 4 must become “a basis of the parties’ bargain.” *Naiser v. Unilever U.S., Inc.*, 975 F. Supp.
 5 2d 727, 737, 740 (W.D. Ky. 2013). Although the *Naiser* court’s full quotation is “direct
 6 representations to consumers,” *id.*, the court’s use of the term “consumers” is because the
 7 case involved a putative class action. *See id.* at 731. But the court’s discussion, in the
 8 context of Kentucky’s requirements for an express warranty under K.R.S. § 355.2-313,
 9 makes clear that a representation must be made directly from a manufacturer to the
 10 plaintiff (or plaintiffs) claiming the express warranty. General representations to
 11 “Kentucky consumers” are not sufficient, when, as here, Plaintiff never saw or heard the
 12 representations.

13 Second, Plaintiff’s attempt to draw a parallel between the facts of this case and the
 14 facts in *Naiser* is unavailing. *Naiser* arose on the defendant’s Rule 12(b)(6) motion to
 15 dismiss, where the court merely had to assess the sufficiency of the plaintiffs’ pleadings.
 16 There, the plaintiffs alleged various representations were made directly to them, and that
 17 they relied on the representations in choosing to purchase the product at issue (a hair
 18 smoothing kit). *Naiser*, 975 F. Supp. 2d at 737-38. Here, Plaintiff points to no record
 19 evidence of any express representation ***made by Bard directly to her***. The list of alleged
 20 representations at page 19 of Plaintiff’s Response Brief are all generic statements, and
 21 there is no evidence that Plaintiff ever saw or heard them. As noted above, she never
 22 received any written information about her filter, never received a patient brochure, never
 23 spoke to anyone at Bard, and she did not review Bard’s website. (*See* Defs.’ Br. at 14
 24 (citing Mulkey Dep. Tr., at 66:23 to 67:1, 67:11-18, 69:24 to 70:1, and 167:11-13
 25 (attached as Ex. E to Defs.’ SSOF)).) Thus, for example, Plaintiff’s citation to what the
 26 Eclipse patient brochure stated, (*see* Pl.’s Resp. at 19), is misplaced and does not support
 27 her KCPA or express warranty claim.

28 Additionally, as argued above at Section C, *supra*, Plaintiff fails to establish that

1 she relied on any direct representation by Bard concerning her filter. In other words, the
 2 alleged representations by Bard did not form the “basis of the bargain” between the
 3 parties. When, as here, a plaintiff does not see or hear a representation from a
 4 manufacturer about a product, said representation cannot, as a matter of law, form the
 5 “basis of the bargain” between the parties. *See Snawder v. Cohen*, 749 F. Supp. 1473,
 6 1481 (W.D. Ky. 1990) (“Plaintiff’s mother never saw the package inserts before her
 7 daughter was vaccinated. Thus, any warranty in the package insert was not part of the
 8 ‘basis of the bargain.’”).

9 Third, Bard respectfully suggests that no exception to the privity requirement
 10 should exist under the KCPA, and the *Naiser* court was mistaken when it read too much
 11 into dicta in *Skilcraft Sheetmetal, Inc. v. Kentucky Mach., Inc.*, 836 S.W.2d 907 (Ky. Ct.
 12 App. 1992) and found such an exception. *Skilcraft*’s holding leaves no room for an
 13 exception. The court stated, “The language of [the KCPA] plainly contemplates an action
 14 by a purchaser against his immediate seller.” *Id.* at 909. The court further explained that
 15 the Kentucky legislature “intended that privity of contract exist between the parties in a
 16 suit alleging a violation of the Consumer Protection Act.” *Id.* In holding that privity is
 17 required, the *Skilcraft* court observed that the privity requirement, in conjunction with a
 18 two-year statute of limitation running from the date of the alleged violation, demonstrates
 19 the legislature’s “lack of concern for a subsequent purchaser who would often purchase
 20 used merchandise more than two years after the violation, as indeed was the case here.”
 21 *Id.*¹⁴ Finally, the *Naiser* court relied on the *Skilcraft* court’s discussion of *Ford Motor Co.*
 22 *v. Mayes*, 575 S.W.2d 480 (Ky. Ct. App. 1978). *See Naiser*, 975 F. Supp. 2d at 743
 23 (“[*Skilcraft*] found certain situations ‘distinguishable . . . such as that presented in *Ford*
 24 *Motor Co. v. Mayes*, Ky. App., 575 S.W.2d 480 (1978), where the defendant (Ford Motor
 25 Company) provides warranties to the ultimate purchaser to repair the item purchased.”

26
 27 ¹⁴ Bard notes that the alleged representations about the Eclipse Filter identified by
 28 Plaintiff in her Response Brief that would give rise to a KCPA claim all occurred more
 than two years before Plaintiff filed her lawsuit in 2016. Thus, her KCPA claim is time-
 barred. *See K.R.S. § 367.220.*

(quoting *Skilcraft*, 836 S.W.2d at 909)). But in *Mayes*, the defendant-manufacturer did not contest the standing of the consumer-plaintiff to bring a KCPA claim even though the consumer purchased the truck from a licensed dealer. *See generally Mayes*, 575 S.W.2d 480. Thus, the lack of privity between the plaintiff and defendant was not an issue resolved by the *Mayes* court.

CONCLUSION

For these reasons, and for the reasons stated in Bard's Opening Brief, Bard respectfully requests that this Court grant Bard's Motion for Summary Judgment.

RESPECTFULLY SUBMITTED this 25th day of October, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of October 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

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